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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/855,402	05/13/1997	CHRISTOPHER BRADFIELD		1652

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EXAMINER	
ULM, JOHN D	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/855,402	Bradfield et al.
Examiner	**Art Unit**
John Ulm	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 10, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-27* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *21-27* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1) The request filed on 28 February of 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/855,402 is acceptable and a CPA has been established. An action on the CPA follows.

2) Claims 21 to 27 are pending in the instant application. Claims 1, 2, 4 to 6, 8 to 12 and 14 to 20 have been canceled and claims 21 to 27 have been added as requested by Applicant in Paper Number 18, filed 28 February of 2001. Claims 21, 22, 26 and 27 have been amended a requested by Applicant in Paper Number 23, filed 10 September of 2001.

3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) The oath or declaration is defective for those reasons of record in section 2 of Paper Number 5 and section 4 of Paper Number 8.

6) Restriction to one of the following inventions is required under 35 U.S.C. 121 for further prosecution on the merits in the instant application:

I. Claim 21, drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:37, classified in class 530, subclass 350.

II. Claim 22, drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:38, classified in class 530, subclass 350.

III. Claims 23 to 25, drawn to a chimeric Ah receptor comprising a heterologous DNA binding domain, classified in class 530, subclass 350.

IV. Claim 26, drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:39, classified in class 530, subclass 350.

V. Claim 27, drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:40, classified in class 530, subclass 350.

The inventions are distinct, each from the other because:

The proteins that are inventions I to V are five different proteins each of which can be made and used without any one or more of the other claimed proteins. Lack of unity is shown by the fact that these five proteins lack a common utility which is based upon a shared structural feature identified a the basis for that common utility and which is lacking from the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined during the further prosecution of the instant application even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7) Claims 21 to 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims. Because claims 21, 22, 26 and 27 recite the limitation "and alterations, substitutions, additions and deletions thereof" in reference to a sequence, the sequence limitations of these claims have no meaning since they allow one to replace ("substitute") the referenced sequence with an entirely different sequence. Therefore, none of the instant claims recite the structural features which define "a DNA binding domain of an Ah receptor". Whereas the claims encompass any protein comprising "a DNA binding domain of an Ah receptor" the instant specification does not provide an adequate written description of the genus of protein encompassed by that term. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow

persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of two naturally occurring Ah receptors having very specific physical and structural properties, the instant specification does not provide a structural formula which is definitive of all Ah receptors. Whereas the instant specification may identify some properties which are common to the two Ah receptors that are disclosed in the instant specification, it does not identify those defining structural elements which provide the functional and structural properties of genus of proteins which would be encompassed by the term "Ah receptor".

Further, the instant specification does not provide the guidance needed to alter either of the two Ah receptor DNA binding domains which are described in the instant specification. The

instant specification does not identify those amino acid residues in SEQ ID NOs:37 and 38 which are critical to the structural and functional integrity of an Ah receptor DNA binding domain and those residues which are expendable. It also fails to identify those amino acid residues in SEQ ID NOs:39 and 40 which are critical to the structural and functional integrity of an Ah receptor ligand binding domain and those residues which are expendable or substitutable. The instant specification does not provide even a single working example an Ah receptor DNA- or ligand-binding domain whose amino acid sequence has been altered at even one residue from the naturally occurring sequences described in the instant specification. And finally, the instant specification does not identify an analogous protein in the prior art for which this information is known and could be applied to an Ah receptor binding domain by extrapolation. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that:

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most

chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Because the instant specification does not provide the guidance needed to predict, "by resort to known scientific law", the effects that specific alterations to the amino acid sequences presented in SEQ ID NOs:37 to 40 will have on the Ah receptor binding domains comprising those sequences, an artisan can not practice the instant invention commensurate with the scope of the claims without first engaging in the substantial undue experimentation that would be required to obtain the structure/function information which is lacking from the instant specification.

8) Claims 21 to 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 21 to 27 are vague and indefinite in so far as they employ the term "Ah receptor" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of an "Ah receptor" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9) Claims 21, 22, 26 and 27 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Ema et al. publication (BIOCHEM. BIOPHYS. RES. COMM. 184(1):246-253, 15 Apr. 1992). Because these claims recite the limitation "and alterations, substitutions, additions and deletions thereof" in reference to a sequence, the sequence limitations of these claims have no meaning since they allow one to replace ("substitute") the referenced sequence with an entirely different sequence. These claims, therefore, encompass any isolated protein which is an "Ah receptor".

10) Claims 21, 22, 26 and 27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Bradfield et al. publication (MOLECULAR PHARMACOLOGY 39(1):13-19, 1991, abstract provided) which was cited in application Serial Number 08/045,806, of which the instant application is a continuation in part. This publication clearly described an isolated Ah receptor more than one year before the filing on the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800